

REMARKS

Claims 1-14 were present in the application as filed and are currently pending and under consideration.

Rejection under 35 U.S.C. §103(a)

Claims 1-14 were rejected under U.S.C. §103(a) as allegedly being unpatentable over Edwardson et al. (U.S. Patent No. 5,763,411) in view of Chen et al. (U.S. Patent No. 6,761,903).

According to the Office Action, it would have been obvious to one of skill in the art to replace the fibrin monomer coating as disclosed by Edwardson et al. with coating agents as disclosed by Chen et al. in order to provide for a method to prevent scarring. Applicant disagrees.

Applicant's claimed method is directed to a method for minimizing scarring and/or preventing excessive scar formation at an injury site. The method comprises applying to the injury site a first aid bandaging material that has been coated with a therapeutically effective amount of a defibrinogenating agent, such as ancrod. It is clear from the specification that the problem the invention seeks to solve is the problem of scarring at a wound site.

The specification (page 1, paragraphs 2 and 3) describes the mechanism by which the invention seeks to remedy the problem of scarring at a wound site. Specifically, fibrin is a protein that initiates blood clots at a wound site and the deposition of fibrin plays a key role in scar formation. The claimed method achieves its result by applying a bandage containing a defibrinogenating agent such as ancrod to the wound site to remove the clotting precursor, fibrinogen, thereby reducing the level of fibrin formation and ultimately fibrin deposition that leads to scarring.

Conversely, Edwardson et al. relates to the development of a non-dynamic fibrin monomer that can be applied to a solid support such as a bandage, and which is readily capable of being converted to a fibrin polymer which can serve as a sealant for wound healing (abstract). Fibrin sealants are biological adhesives whose effect imitates the final

stages of coagulation (col. 1, lines 62-64.) Conventional fibrin sealants are generated by combination of various blood components including concentrated human fibrinogen prepared from pooled human plasma and bovine thrombin, both sources prone to contamination by viruses. The goal of Edwardson, therefore is the production of a fibrin sealant that can be delivered to a patient without the risk of viral contamination. Edwardson et al. accomplishes this by preparation of a fibrin composition comprising non-dynamic non-crosslinked fibrin monomer that can be applied to a solid support such as a bandage and ultimately (when applied to the wound) converted to a fibrin clot to facilitate wound healing at the site.

In contrast, Applicant's claimed method for minimizing scarring requires directly applying a bandage that contains a defibrinogenating agent to the site to *reduce* the levels of fibrin at the site, not to apply fibrin to the site as taught by Edwardson et al.

Thus, Edwardson et al. teaches away from the present invention.

Chen et al. relates to drug delivery and in particular a drug delivery composition that enhances solubility of therapeutic agents and forms a clear aqueous dispersion upon mixing with an aqueous medium. Though Chen et al. teaches that in one embodiment, the dosage forms may be processed by techniques selected from a group that includes "coating," there is no teaching or suggestion in Chen et al. regarding the desirability of coating bandage material or sutures with a defibrinogenating agent, and no teaching or suggestion that administration of defibrinogenating agent to an injury is efficacious for minimizing scarring at the injury site. Thus, Chen et al. is inapposite to the present invention.

The teachings of Chen et al. do not compensate for the shortcomings of the teachings of Edwardson et al. Chen et al. teaches a pharmaceutical composition for improved solubilization of triglycerides and improved delivery of all types of therapeutic agents, including fibrinolytic agents. Chen et al. relates to improved delivery of therapeutic agents by virtue of the improved solubilization of the agents in a formulation containing triglyceride(s) and surfactant(s). In contrast to the instant invention which relates to direct application of a defibrinogenating agent to an injury site Chen teaches coating with agents including fibrinolytic agents, the focus of Chen is on improved absorption across "mucosal membranes in the nasal cavity, in the oral cavity, in the gastrointestinal tract, in the lungs"


(col 48, 22-24) not absorption from a bandage to an area of local injury claimed on the instant invention.

Since Edwardson et al. actually teaches away from the desirability of preventing clot formation or inducing clot lysis, there would be no motivation for one of skill in the art to combine the teaching of Edwardson with the teachings of Chen et al. In any event, either individually or in combination, the teachings of Edwardson and Chen do not result in Applicant's claimed method.

Withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

It is believed that the application is in condition for allowance, and such action is respectfully requested. If a telephone conference would be of assistance in advancing the prosecution of the subject application, the Examiner is invited to telephone applicant's undersigned attorney at the number provided below.

Respectfully submitted,


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